



TOY 117.007APC

FW Receipt

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nakayama, et al.

Group Art Unit 1653

Appl. No. : 10/563,540

## CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

Filed : December 22, 2005

June 30, 2006

For : METHOD OF DETECTING CANCER

(Date)

Examiner : Unknown

*Che S. Chereskin*  
Che Swyden Chereskin, Ph.D., Reg. No. 41,466

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents  
P.O. Box 1450  
Office of Initial Patent Examination  
Customer Service Center  
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby request that the Official Filing Receipt, a copy of which is enclosed, be corrected to reflect the foreign priority data. We are enclosing herewith a copy of the Preliminary Amendment, Declaration and Power of Attorney and Form PCT/IB/304 which cite Japanese application 2003-185696, filed on June 27, 2003, as the foreign priority application.

Respectfully submitted,

KNOBBE, MARTENS, OLSON &amp; BEAR, LLP

Dated: June 30, 2006By: *Che S. Chereskin*

Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
(949) 760-0404

2712719  
062606

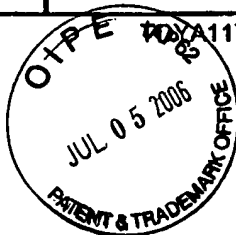


## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/563,540	12/22/2005	1653	900	117.007APC	1	9	3

20995  
 KNOBBE MARTENS OLSON & BEAR LLP  
 2040 MAIN STREET  
 FOURTEENTH FLOOR  
 IRVINE, CA 92614



CONFIRMATION NO. 8669

## FILING RECEIPT



\*OC000000019309931\*

Date Mailed: 06/22/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Jun Nakayama, Matsumoto-shi, JAPAN;  
 Satoshi Ishizone, Matsumoto-shi, JAPAN;

Power of Attorney: The patent practitioners associated with Customer Number 20995.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP04/09126 06/28/2004

Foreign Applications JAPAN 2003-185696 06/27/03

If Required, Foreign Filing License Granted: 06/16/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/563,540**

Projected Publication Date: 09/28/2006

Non-Publication Request: No

Early Publication Request: No

## Title

Method of detecting cancer

**BEST AVAILABLE COPY**

**Preliminary Class**

435

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but **does not result in a grant of "an international patent"** and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

---

**LICENSE FOR FOREIGN FILING UNDER****Title 35, United States Code, Section 184****Title 37, Code of Federal Regulations, 5.11 & 5.15****GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

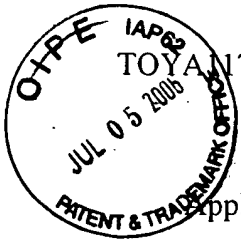
**BEST AVAILABLE COPY**

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**BEST AVAILABLE COPY**



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nakayama, et al.  
Int'l Appl. No. : PCT/JP2004/009126  
Int'l filing date : June 28, 2004  
For : METHOD OF DETECTING  
CANCER  
Examiner : unknown  
Group Art Unit : unknown

PRELIMINARY AMENDMENT

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Preliminary to examination on the merits, please amend the above-captioned U.S. application as follows.

**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 5 of this paper.

Int'l Appl. No. : PCT/JP2004/009126  
Int'l filing date : June 28, 2004

#### AMENDMENTS TO THE SPECIFICATION

*On page 1 of the Specification, after the Title of the Invention and before the Technical Field statement starting on line 1, please insert the following section:*

[Related applications]

This application is the U.S. National Phase under 35 U.S.C. § 371 of International Application PCT/JP2004/009126, filed June 28, 2004, which was published in a language other than English, which claims priority of JP Application No. 2003-185696, filed June 27, 2003.

*On page 11 before Claim 1, please amend as follows:*

~~Claims~~ WHAT IS CLAIMED IS:

Int'l Appl. No. : PCT/JP2004/009126  
Int'l filing date : June 28, 2004

### AMENDMENTS TO THE CLAIMS

Claim 1. (Currently amended) A method of detecting cancer comprising measuring the expression level of  $\alpha$ - $\alpha$ -1,4-N-acetyl-D-glucosamine transferase gene in a body fluid collected from a living body to correlate the measurement value with the presence or absence, development, degree of progress, or prognosis of cancer, wherein expression level of said gene is measured by detecting an arbitrary region consisting of continuous nucleotides having a length of 70 to 139 bp in the nucleotide sequence of SEQ ID NO: 1.

Claim 2. (Original) The method of detecting cancer according to Claim 1, wherein said region is a region consisting of a nucleotide sequence of nucleotide numbers from 520 to 628 of SEQ ID NO: 1.

Claim 3. (Currently amended) The method of detecting cancer according to Claim 1-~~or~~-2, wherein said body fluid is blood or lymph.

Claim 4. (Currently amended) The method of detecting cancer according to ~~any one of Claims 1 to 3~~Claim 1, wherein said cancer is one or more cancers selected from the group consisting of salivary gland cancer, esophageal cancer, stomach cancer, pancreatic cancer, gallbladder cancer, small intestine cancer, colon cancer, and rectal cancer.

Claim 5. (Currently amended) The method of detecting cancer according to ~~any one of Claims 1 to 3~~Claim 1, wherein said cancer is pancreatic cancer.

Claim 6. (Currently amended) A method of determining a degree of progress of pancreatic cancer comprising measuring the expression level of  $\alpha$ - $\alpha$ -1,4-N-acetyl-D-glucosamine transferase gene in a body fluid collected from a living body to correlate the measurement value with the degree of progress of the pancreatic cancer, wherein the expression level of said gene is measured by detecting an arbitrary region consisting of continuous nucleotide sequence having a length of 70 to 139 bp in the nucleotide sequence of SEQ ID NO: 1.

**Int'l Appl. No. : PCT/JP2004/009126**  
**Int'l filing date : June 28, 2004**

Claim 7. (Original) The method of determining a degree of progress of pancreatic cancer according to Claim 6, wherein said region is a region consisting of a nucleotide sequence of nucleotide numbers from 520 to 628 in SEQ ID NO: 1.

Claim 8. (Currently amended) The method of determining a degree of progress of pancreatic cancer according to Claim 6-~~or~~7, wherein said body fluid is blood or lymph.

Claim 9. (Original) A kit for detecting cancer, comprising primers for amplifying an arbitrary region consisting of continuous nucleotide sequence having a length of 70 to 139 bp in the nucleotide sequence of SEQ ID NO: 1.



Int'l Appl. No. : PCT/JP2004/009126  
Int'l filing date : June 28, 2004

### REMARKS

The claims have been amended to conform with the rules of practice before the U.S. Patent and Trademark Office and to make minor corrections. The specification has been amended to recite the International Application and priority application. The word "CLAIMS" has been deleted and substituted by "WHAT IS CLAIMED IS" so that subsequently appearing claims will be the object of a sentence as specified by M.P.E.P. section 608.01(m). As a result of this preliminary amendment, Claims 1, 3-6, and 8 have been amended. Accordingly, Claims 1-9 are presented for examination. No new matter is being added herewith.

### Conclusion

Should there be any questions concerning this application, the Examiner is invited to contact the undersigned agent at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

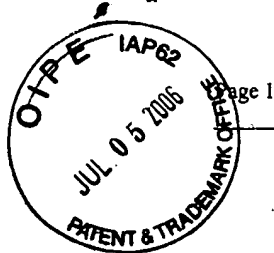
Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Dec. 22, 2005

By: Che S. Chereskin  
Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
(949) 760-0404

2239371  
122205



TOYAH7.007APC F200411(P)  
(OP-C4109-PC-US)

Attorney's Docket No. \_\_\_\_\_

2005  
JUN 21  
14:58

# DECLARATION AND POWER OF ATTORNEY - USA PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is

sought on the invention entitled

METHOD OF DETECTING CANCER

the specification of which:

- (a) ☐ is attached hereto; or
- (b) ☐ was filed on \_\_\_\_\_ as Application  
No. \_\_\_\_\_ or Express Mail No., as Application No. not  
yet known \_\_\_\_\_ and was amended  
on \_\_\_\_\_ (if applicable); or
- (c) ☒ was described and claimed in PCT International Application No.  
\_\_\_\_\_ PCT/JP2004/009126 filed on June 28, 2004  
and as amended under PCT Article 19 on \_\_\_\_\_  
(if any) and/or under PCT Article 34 on \_\_\_\_\_ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56;

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) listed below and have also identified below any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed for the same subject matter having a filing date before that of the application(s) of which priority is claimed:

## PRIOR FOREIGN APPLICATION(S)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 U.S.C. § 119	
Japan	2003-185696	27, June, 2003	<input checked="" type="radio"/> YES	NO <input type="radio"/>
			<input type="radio"/> YES	NO <input type="radio"/>
			<input type="radio"/> YES	NO <input type="radio"/>
			<input type="radio"/> YES	NO <input type="radio"/>

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I

Page 2

Attorney's Docket No. TOYAMA.ODT APC

acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application(s)

Application No.: \_\_\_\_\_ Filing Date: \_\_\_\_\_ Status: \_\_\_\_\_

POWER OF ATTORNEY: I hereby appoint the registrants of Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, Sixteenth Floor, Newport Beach, California 92660, Telephone (949) 760-0404, Customer No. 20,995.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Jun NAKAYAMAInventor's signature: Jun Nakayama Day 10 Month 11 Year 2005Residence (city and country): Matsumoto-shi, JapanCitizenship: JapanesePost Office Address: Room 301, Agatajutaku, 9-2, Agata 1-chome, Matsumoto-shi, Nagano 390-0812 JapanFull name of second inventor: Satoshi ISHIZONEInventor's signature: Satoshi Ishizone Day 10 Month 11 Year 2005Residence (city and country): Matsumoto-shi, JapanCitizenship: JapanesePost Office Address: Room 407, Gardenhatsu Matsumoto, 9-6, Kitahukashi 3-chome, Matsumoto-shi, Nagano 390-0872 Japan

Full name of third inventor: \_\_\_\_\_

Inventor's signature: \_\_\_\_\_ Day \_\_\_\_\_ Month \_\_\_\_\_ Year \_\_\_\_\_

Residence (city and country): \_\_\_\_\_

Citizenship: Japanese

Post Office Address: \_\_\_\_\_

Send Correspondence To:  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
Customer No. 20,995  
PF-33

PCT/JP2004/009126

# PATENT COOPERATION TREATY

PCT

from the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT  
(PCT Administrative Instructions, Section 411)

KAWAGUCHI, Yoshiyuki  
Acropolis 21 Building 6th floor, 4-  
10, Higashi Nihonbashi 3-chome,  
Chuo-ku, Tokyo  
1030004  
Japan

Date of mailing (day/month/year) 27 September 2004 (27.09.2004)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference F200411C4109	
International application No. PCT/JP2004/009126	
International publication date (day/month/year) Not yet published	
Applicant SEIKAGAKU CORPORATION et al	International filing date (day/month/year) 28 June 2004 (28.06.2004)
	Priority date (day/month/year) 27 June 2003 (27.06.2003)

- By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- (If applicable) The letters "NR" appearing in the right-hand column denote a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- (If applicable) An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b) (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
27 June 2003 (27.06.2003)	2003-185696	JP	19 Augu 2004 (19.08.2004)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Patrick BLANCO (Fax 338 9090)
Facsimile No. (41-22) 338.90.90	Telephone No. (41-22) 338 8702

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record.**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☒ **BLACK BORDERS**

☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

☐ **FADED TEXT OR DRAWING**

☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☐ **SKEWED/SLANTED IMAGES**

☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**